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MAY 22 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Firm: Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, MA 01104

510(k) Contact: Alan Lombardo
Director of Engineering

Trade Name: Blackstone™ III° Anterior Cervical Plating System

Common Name: Cervical Plating Instrumentation

Device Product Code & Classification: **KWQ** 888.3060 - Spinal Intervertebral Body Fixation Orthosis

Substantially Equivalent Devices:

Blackstone™ III° Anterior Cervical Plating System (K012184)
Blackstone™ Anterior Cervical Plate System (K974885)

Device Description:

The Plate Washer addition for the Blackstone™ III° Anterior Cervical Plating System is a titanium alloy (6AL-4V ELI, per ASTM F136) device which is a non-sterile, single use component. When used with the Blackstone™ III° Anterior Cervical Plating System a surgeon can build an anterior cervical implant construct. The system's design is intended to stabilize the cervical spinal operative site during the fusion process of a bone graft in the disc space.

Intended Use / Indications for Use:

Blackstone™ III° Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

a) degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) spondylolisthesis;
c) fracture;
d) spinal stenosis;
e) deformities (i.e., scoliosis, kyphosis, and/or lordosis);
f) tumor;
g) pseudarthrosis;
h) revision of previous surgery

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Plate Washer addition for the Blackstone™ III° Anterior Cervical Plating System by its very nature is substantially equivalent to the predicate devices listed below:

Blackstone™ III° Anterior Cervical Plating System (K012184)
Blackstone™ Anterior Cervical Plate System (K974885)

The FDA has cleared each of these devices, for anterior fixation to the cervical spine from C2 to C7.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Mr. Alan Lombardo
Director of Engineering
Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, Massachusetts 01104

Re: K020600
Trade/Device Name: Blackstone™ III° Anterior Cervical Plating System (Plate Washer)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 21, 2002
Received: February 22, 2002

Dear Mr. Lombardo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K020600

Device Name: *Blackstone™ III° Anterior Cervical Plating System*

Indications for Use:

Blackstone™ III° Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

a) degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
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c) fracture;
d) spinal stenosis;
e) deformities (i.e., scoliosis, kyphosis, and/or lordosis);
f) tumor;
g) pseudarthrosis;
h) revision of previous surgery

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020600